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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/677,303 | 10/03/2003 | Helene Strick-Marchand | 242258US | 9631 |
| 22850 | 7590 | 03/30/2006 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | AFREMOVA, VERA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
| DATE MAILED: 03/30/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------|------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/677,303 | STRICK-MARCHAND ET AL. | |
| | Examiner Vera Afremova | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 5-7,12-21,24-35 and 38-46 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,8-11,22,23,36 and 37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of the Group I, drawn to a mammalian hepatic cell line, and election of species such as undifferentiated non-transformed mammalian hepatic cell line in the reply filed on 12/19/2005 is acknowledged. The traversal is on the ground(s) that there is no serious burden in searching and examining all claims. This is not found persuasive because different groups of claims and species are drawn to products and methods having different scope as claimed and, thus, the references that would be applied to one group of claims or species would not necessarily anticipate or render obvious the other claims. Moreover, the literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 5-7, 12-21, 24-35 and 38-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction/election requirement in the reply filed on 12/19/2006.

Claims 1-4, 8-11, 22, 23, 36 and 37 are under examination in the instant office action.

Information Disclosure Statement

The information disclosure statement filed 10/03/2003 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or

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other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

The IDS paper dated 10/03/2003 states that Form 1449 with listing of references is attached. But the instant IFW application is lacking this forms. Please, provide a copy of Form 1449 together with copies of missing references cited therein.

Claim Rejections - 35 USC § 112

Deposit

Claims 22 and 23 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific cell lines that are BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099). Because the cell lines are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be

satisfied by deposit of the cell lines. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the cell lines are readily available to the public.

The rejection may be overcome by establishing that each cell line is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because CNCM has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions imposed by the depositor on availability to the public of the deposited cell lines BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099) will be irrevocably removed upon issuance of the patent will overcome this rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 8-11, 22, 23, 36 and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims as written, do not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any naturally occurring differences between the claimed products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 393, 206 USPQ 193 (1980).

The claims should be amended to indicate the hand of inventor. e.g., by insertion of “Isolated” or “An isolated” as taught on page 8, line 16 of specification. See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-11, 22, 23, 36 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Strick-Marchand et al. (Hepatology. October 2002. Vol. 36, NO. 4, pages 794-804.).

Claims are directed to a cultured immortalized non-transformed mammalian hepatic cell line. Some claims are further drawn to the cells being undifferentiated cells or stem cells or bipotential cells. Some claims are further drawn to the mammalian mouse cells or mammalian embryonic liver cells. Some claims are further drawn to the cells obtained by culturing 2-3

mounts. Some claims are further drawn to the cells being cell lines BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099).

The reference by Strick-Marchand et al. discloses immortalized non-transformed mammalian hepatic cell lines that are undifferentiated bipotential cells derived from mouse embryonic liver cells including cell lines BMEL-14B3 and BMEL-9A1 (table 3). The cells were cultured for at 2-3 mounts (table 1). The cited reference anticipates the claimed invention.

Claims 1-4, 8-11, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Spagnoli et al. (The Journal of cell Biology. November 1998. Vol.143, No. 4, pages 1101-1112.).

Claims are directed to a cultured immortalized non-transformed mammalian hepatic cell line. Some claims are further drawn to the cells being undifferentiated cells or stem cells or bipotential cells. Some claims are further drawn to the mammalian mouse cells or mammalian embryonic liver cells. Some claims are further drawn to the cells obtained by culturing 2-3 mounts.

Spagnoli et al. discloses a immortalized non-transformed hepatic cell (entire document including abstract) that are obtained by culturing hepatic cells derived from liver of mice (page 1102 at section Materials and Methods). The cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-11, 22, 23, 36 and 37 are rejected under 35 U.S.C. 102(b) as anticipated by Spagnoli et al. (The Journal of cell Biology. November 1998. Vol.143, No. 4, pages 1101-1112.).or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spagnoli et al. (The Journal of cell Biology. November 1998. Vol.143, No. 4, pages 1101-1112.).

Claims are directed to a cultured immortalized non-transformed mammalian hepatic cell line. Some claims are further drawn to the cells being undifferentiated cells or stem cells or bipotential cells. Some claims are further drawn to the mammalian mouse cells or mammalian embryonic liver cells. Some claims are further drawn to the cells obtained by culturing 2-3 mounts. Some claims are further drawn to the cells being cell lines BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099).

The cited reference by Spagnoli et al. is relied upon as explained above. The cited reference is silent about particular cell lines identified by designation numbers BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099).

Thus, referenced hepatic cells appear to be identical to the presently claimed cell lines and are considered to anticipate the claimed cell lines since they are disclosed as being cultured immortalized non-transformed mammalian bipotential hepatic cells.

In the alternative, even if the claimed cell lines are not identical to the referenced cells with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced cells are likely inherently possess the same characteristics of the claimed cells particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed cell lines would have

been obvious to those of ordinary skill in the art within the meaning of USC 103. Therefore, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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February 28, 2006



VERA AFREMOVA

PRIMARY EXAMINER